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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,763	11/17/2000	Victor E. Shashoua	CMX-001. US	7035
7590	06/02/2004		EXAMINER	
Brown Raymond Millstein Felder & Steiner 900 Third Avenue New York, NY 10022			DESAI, ANAND U	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/715,763	SHASHOUA, VICTOR E.	
	Examiner	Art Unit	
	Anand U Desai, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 88, 92, 93, 95-99 and 104-117 is/are pending in the application.
- 4a) Of the above claim(s) 110-117 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 88, 92, 93, 95-99, 104-106, 108, and 109 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to Amendment filed April 15, 2004. Claims 89-91, 94, 100-103 have been cancelled. Claims 110-117 are withdrawn. Claims 88, 92, 93, 95-99, and 104-109 are currently pending and are under examination.

Priority

1. Applicant's claim for domestic priority to U.S. Provisional Application Serial Number 60/166,381, filed November 18, 1999, under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 88, 89, 92, 93, 95-99 of this application. The provisional application does not disclose the chemical composition capable of upregulating glutathione peroxidase. Therefore, the priority date is the filing date, November 17, 2000.

Response to Applicants Remarks

Applicants respectfully submits that the provisional application no. 60/166,381, which the instant application claims priority to, describes glutathione peroxidase, and is entitled to a priority date of November 18, 1999. This is unpersuasive. The provisional application no. 60/166,381 does not provide adequate support under U.S.C. 112 for claims 88, 89, 92, 93, 95-99 of this application, because within both the Summary of the Invention and Detailed Description sections of the provisional application there is no mention to the discovery of peptide compounds that upregulate glutathione peroxidase. Rather both the Summary of the Invention and Detailed Description of the provisional application disclose the peptide compounds stimulate expression of superoxide dismutase (SOD) and catalase (CAT) (see 60/166,381, page 4, line 23 to page 11,

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line 8, and page 13, line 18 to page 14, line 2 as well as page 16, line 24 to page 17, line 11).

Therefore, the priority date is the filing date, November 17, 2000.

Withdrawal of Rejections

The rejection of claim 99 under 35 U.S.C. §112, second paragraph as being indefinite is withdrawn.

Maintenance of Objections and Rejections

Claim Objections

2. Claims 88, and 109 are objected to because of the following informalities: Claims 88, and 109 have typographical errors. The word “perioxidase” appears to be intended to be “peroxidase”.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 88, 92, 93, 95-99, 104-106, 108, and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shashoua, V. U.S. Patent 6,627,601 (Effective filing date=February 10, 1998) in view of Jornot et al. (Biochem. J. 1997 326:117-123) and in further view of Thomas et al. U.S. Patent 5,972,985 (Effective filing date=November 3, 1997). Shashoua, V. teach the method of increasing neuronal activator protein-1 (AP-1) transcription factor comprising administering an isolated polypeptide (U.S. Patent ‘601, claim 1). The polypeptide can be a

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modified version of Asp Gly Asp Gly Asp Phe Ala Ile Asp Ala Pro Glu (U.S. Patent '601, SEQ ID NO:1). The modification can be the deletion of one or more of the terminal calcium coordination residues. The modification results in a polypeptide which has a reduced length as compared to the original peptide (U.S. Patent '601, see column 6, lines 36-47, current application, claims 88, 92, 93, 104, and 105). Shashoua, V. also teach the conjugation of the isolated polypeptide to compounds which facilitate transport across the blood-brain barrier (BBB), such as docosahexaenoic acid group (DHA), polylysine, and polyarginine (U.S. Patent '601, see column 12, line 47 through column 12, line 9, current application, claims 88, 92, 93, 95-98). Shashoua, V. also teach a pharmaceutical composition which comprises an isolated polypeptide and a pharmaceutically acceptable carrier (U.S. Patent '601, see column 3, lines 61-65, current application, claims 88, and 106). Shashoua, V. does not teach the administration of an isolated polypeptide that is capable of upregulating an antioxidative enzyme. Jornot et al. teach the upregulation of glutathione peroxidase, an antioxidative enzyme, due to the presence of tumor promoting agent responsive elements (TREs). TRE is the binding site for the transcription factor activator protein-1 (AP-1) (see page 117, Introduction 2nd paragraph and page 122, Discussion 3rd paragraph, current application, claims 88, 99, and 109). Thomas et al. teach nutraceutical compositions that contain a plant source useful as a dietary supplement which have antioxidant properties (U.S. Patent '985, column 1, lines 50-63, current application, claims 106, and 108). One would have been motivated to prepare a dietary supplement or pharmaceutical composition comprising a modified polypeptide as taught by Shashoua, V., which increases AP-1 expression and thereby upregulates an antioxidative enzyme, glutathione peroxidase, with a pharmaceutical acceptable excipient to reduce the toxic affects associated with oxidative free

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radicals. Therefore, it would have been obvious to the person having ordinary skill in the art to prepare a pharmaceutical composition consisting of a peptide compound and a suitable vehicle by mixing the peptide compound with a suitable vehicle (current application, claims 88, 92, 93, 95-99, 104-106, 108, and 109).

Response to Applicants Remarks

5. The Shashoua U.S. Patent 6,627,601 has an effective filing date of February 10, 1998, and the priority date of the current application is November 17, 2000. The Shashoua patent is prior art. The comments in the response are unpersuasive because the cited portions of particular relevance of a reference were cited so as to disclose the level of knowledge in the prior art that teach or suggest the claim limitations of the current application when the references are combined. Particularly, the Jornot et al. reference shows the upregulation of glutathione peroxidase due to transcription factor activator protein-1 (AP-1) (see page 117, Introduction 2nd paragraph and page 122, Discussion 3rd paragraph), and Shashoua (U.S. Patent '601) discloses the administration of an isolated peptide to increase activity of AP-1, thereby upregulating glutathione peroxidase (see U.S. Patent '601, claim 1). Furthermore, Thomas et al. (U.S. Patent '985) disclose nutraceutical compositions which are useful as dietary supplements that have antioxidant properties (see U.S. Patent '985, column 1, lines 50-63). One would have been motivated to prepare a dietary supplement or pharmaceutical composition comprising a modified polypeptide as taught by Shashoua, V., which increases AP-1 expression and thereby upregulates an antioxidative enzyme, glutathione peroxidase, with a pharmaceutical acceptable excipient to reduce the toxic affects associated with oxidative free radicals. Therefore, it would have been

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obvious to the person having ordinary skill in the art to prepare a pharmaceutical composition consisting of a peptide compound and a suitable vehicle by mixing the peptide compound with a suitable vehicle (current application, claims 88, 92, 93, 95-99, 104-106, 108, and 109).

References cited

Applicant has received all references in previous office action.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

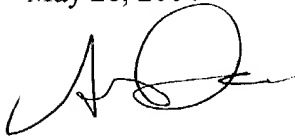
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai whose telephone number is (703) 305-4443. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

May 28, 2004

A handwritten signature in black ink, appearing to be "A. O.", written below the date.A handwritten signature in black ink, appearing to be "Christopher S. F. Low", written above the printed name.

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600